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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,517	10/31/2003	Dale B. Schenk	015270-008920US	8113

20350 7590 02/02/2005

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EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/699,517	SCHENK ET AL	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **2-16, 36-40, 45-55,** and **68,** drawn to a method for preventing or treating a disease characterized by Lewy bodies or alpha-synuclein aggregation comprising administering an agent which induces an *immunogenic response against alpha-synuclein* wherein said agent is alpha-synuclein, classified in class 424, subclass 187.1, for example.

II. Claims **2, 8-10, 18-29, 33-40, 45-55,** and **68,** drawn to a method for preventing or treating a disease characterized by Lewy bodies or alpha-synuclein aggregation comprising administering an agent which induces an *immunogenic response against alpha-synuclein* wherein said agent is an antibody, classified in class 424, subclass 130.1, for example.

III. Claims **2, 8-10, 30-40, 45-55,** and **68,** drawn to a method for preventing or treating a disease characterized by Lewy bodies or alpha-synuclein aggregation comprising administering an agent which *induces an immunogenic response against alpha-synuclein* wherein said agent is a polynucleotide, classified in class 514, subclass 44, for example.

IV. Claims **42** and **45-55,** drawn to a method for preventing or treating a disease characterized by Lewy bodies or alpha-synuclein aggregation comprising administering an agent which induces an *immunogenic response against Aβ*

wherein said agent is alpha-synuclein, classified in class 424, subclass 187.1, for example.

V. Claims 43 and 45-55, drawn to a method for preventing or treating a disease characterized by Lewy bodies or alpha-synuclein aggregation comprising administering an agent which induces an *immunogenic response against Aβ* wherein said agent is an antibody, classified in class 424, subclass 130.1, for example.

VI. Claims 57, 61, and 69-70, drawn to a pharmaceutical composition comprising an antibody, classified in class 530, subclass 387.1, for example.

VII. Claims 58-61 and 69-70, drawn to a pharmaceutical composition comprising alpha-synuclein, an immunogenic alpha-synuclein, 6CHC-1, or an immunogenic 6CHC-1 fragment, classified in class 530, subclass 300, for example.

VIII. Claims 62-67, drawn to a method of screening for an antibody for activity in preventing or treating a disease associated with Lewy bodies, classified in class 435, subclass 7.21, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Claims 1 link(s) inventions I, II, III, IV, and V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s)

are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Claim 17 link(s) inventions IV and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 17. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. Claims 41 and 44 link(s) inventions IV and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 41 and 44. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the

allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Claim 56 link(s) inventions VI and VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 56. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the

following reasons. Inventions VI and VII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Although the antibody of Invention VI can be used to purify the proteins of Invention VII, it is independent and distinct from Invention VII because it can be used in other materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography) or therapeutic methods. The proteins of Invention VII are independent and distinct from Invention VI because they can be prepared by processes which are materially different from the antibody of Invention VI, such as by chemical synthesis or by isolation and purification from natural sources.

8. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, III, IV, V, and VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other.

9. Inventions I and IV are drawn to active immunization which is independent and distinct from Inventions II and V which are drawn to passive immunization. Active immunization requires search and consideration of administering an immunogenic agent to induce an immune response while passive immunization requires search and consideration of administering antibodies as a therapeutic. Thus Inventions I and IV and II and V are drawn to distinct and independent Inventions which occupy separate statuses in the art and have non-overlapping fields of search. Furthermore, Invention III is drawn to gene therapy which is independent and distinct from Inventions I, II, IV, and V. Gene therapy requires search and consideration of

administering a polynucleotide as a therapeutic agent which is not required by Inventions, I, II, IV, and V. Thus Invention III and Inventions I, II, IV, and V occupy separate statuses in the art and have non-overlapping fields of search.

10. Inventions I, II, and III are drawn to inducing an immunogenic response against alpha-synuclein which is independent and distinct from Inventions IV and V which are drawn to inducing an immunogenic response against Aβ. Alpha-synuclein and Aβ, the (presumed) causative agents of two different neurodegenerative diseases do not share a common structure or pathology (function) as both neurodegenerative disease is independent, distinct, and non-obvious over one another. For instance, Aβ is related to Alzheimer's disease, which is unrelated to Parkinson's disease. To date, Parkinson's disease has not known cause and is characterized by the loss of dopaminergic neurons in the substantia nigra pars compacta, which is unrelated to the Alzheimer's disease. Furthermore, Lewy bodies and alpha-synuclein are currently believed to be associated with Parkinson's disease and are thus are independent and distinct fields of search from Alzheimer's disease. As such each disease requires a separate and non-overlapping search of the literature and patent databases.

11. In addition, Invention VIII is drawn to a screening method which is independent and distinct from each of Inventions I, II, III, IV, and V which are all therapy methods.

12. Therefore, Invention I requires search and consideration of using alpha-synuclein as a therapeutic to induce an immunogenic response against alpha-synuclein, which is not required by Inventions II, III, IV, V, or VIII. Invention II requires search and consideration of using an antibody as a therapeutic to induce an immunogenic response against alpha-synuclein, which is not required by Inventions I, III, IV, V, or VIII. Invention III requires search and consideration

of using a polynucleotide as a therapeutic to induce an immunogenic response against alpha-synuclein, which is not required by Inventions I, II, IV, V, or VIII. Invention IV requires search and consideration of using alpha-synuclein as a therapeutic to induce an immunogenic response against Aβ, which is not required by Inventions I, II, III, V, or VIII. Invention V requires search and consideration of using an antibody as a therapeutic to induce an immunogenic response against Aβ, which is not required by Inventions I, II, III, IV, or VIII. Invention VIII requires search and consideration of a screening method, which is not required by Inventions I, II, III, IV, or V. Therefore, a search and examination of an Invention as it pertains to both diseases and Inventions would therefore present the examiner with an undue search burden.

13. Inventions VI and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and I are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention I does not recite the use or production of the pharmaceutical composition of Invention VI.

14. Inventions VI and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention VI can be used in materially different methods such as diagnostics or to purify proteins from natural sources.

15. Inventions VI and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and III are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention III does not recite the use or production of the pharmaceutical composition of Invention VI.

16. Inventions VI and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and IV are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention IV does not recite the use or production of the pharmaceutical composition of Invention VI.

17. Inventions VI and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention VI can be used in materially different methods such as diagnostics or to purify proteins from natural sources.

18. Inventions VIII and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the

instant case the antibodies can be made through materially different methods such as chemical synthesis or recombinant cloning.

19. Inventions VII and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention VII can be used in materially different methods such as make antibodies.

20. Inventions VII and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and II are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention II does not recite the use or production of the pharmaceutical composition of Invention VII.

21. Inventions VII and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and III are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention III does not recite the use or production of the pharmaceutical composition of Invention VII.

22. Inventions VII and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention VII can be used in materially different methods such as make antibodies.

23. Inventions VII and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and V are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention V does not recite the use or production of the pharmaceutical composition of Invention VII.

24. Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and VIII are unrelated product and method, wherein each is not required, one for another. For example, the claimed method of Invention VIII does not recite the use or production of the pharmaceutical composition of Invention VII.

25. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

26. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

27. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

28. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

29. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

30. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (BBC) at **866-217-9197** (toll-free).

CJN
January 11, 2005